



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,072	07/17/2003	Kathryn E. Uhrich	01435.028US1	5968
53137 7590 05/13/2009 VIKSININS HARRIS & PADYS PLLP P.O. BOX 111098 ST. PAUL, MN 55111-1098				
EXAMINER				
FINN, MEGHAN R				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
05/13/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,072

Applicant(s)

UHRICH ET AL.

Examiner

MEGHAN FINN

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-14 and 67-77 is/are pending in the application.
4a) Of the above claim(s) 8 and 77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 12-14, and 67-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's Amendment filed February 19, 2009 has been received and entered into present application. Claims 10-11 and 15-66 were canceled and claims 67-74 were added by applicant. Claims 8 and 77 are withdrawn for pertaining to the non-elected species. Thus claims 1-7, and 9, 12-14, and 67-76 are pending.

Applicants' arguments, filed February 19, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The amendments to the claims have rendered moot the previous rejections of record and all the new rejections detailed below were necessitated by the amendments to the claims.

Claim Rejections - 35 USC § 112

(New grounds of rejection necessitated by amendment)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 67-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 67-76 contain new matter. Applicant has added these claims and in claim 67 claims "wherein the polymeric sheet has ridges or spacers that are configured to optimally guide the growth and extension of the neural tissue". Applicant points to page 9 of the specification for support, however on page 9 applicants describes the ridges and spaces being configured to guide the growth and extension of neural processes, not tissue (page 9, lines 15-16). There is no support for specifically guiding neural *tissue*. Additionally, in claims 70-76, applicant claims specific length and diameters of the polymeric sheet and tube. Applicant points to pages 9-10 of the specification for support and yet the only lengths or numbers at all mentioned are directed towards the length of the ridges or spaces and not the sheets or tubes (page 9, lines 21-25). Applicant does mention the lengths of "jellyroll" tubes to be the lengths in claims 70-72, however those lengths are not referring to polymeric sheets. There does not appear to be support anywhere in the specification for claims 67 or 70-76, and since claims 68-72 depend on claim 67 and thus also contain the new matter of claim 67, all claims 67-76 are rejected for containing new matter that is not supported by the original disclosure.

Claims 67-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 67-76, applicant claims a specific form for the polymer of claim 1, where there is a polymeric sheet that is rolled into a tube with linear ridges or spacers and specific lengths and diameters. Applicant has not shown how to make this specific formulation and polymeric sheets with multiple linear ridges does not appear to be well known in the art, especially for the type of biodegrading polymer of claim 1. Applicant has provided no direction and no examples towards how to make the polymer in this specific form and therefore there would be an undue amount of experimentation necessary to formulate this specific tube polymer. The state of the prior art is such that this type of polymer formulation is not well known and while the skill of one in the art is high it would go beyond the limits of routine experimentation to develop the polymer claimed in claims 67-76 and thus they are rejected for lack of an enabling disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 9 and 12-14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Giroux (US 2006/0057179 A1).

Claim 1 claims a device comprising a tube or polymeric sheet that is rolled into a tube which comprises a biodegradable polymer that degrades to provide release of an anti-inflammatory compound. Applicant has elected salicylic acid as the anti-inflammatory and thus claims 1-7 and 9 read upon a tube comprising a biodegradable polymer that degrades to provide release of salicylic acid. Giroux teaches polymers which degrade to provide bioactive compounds (abstract). Giroux further teaches that the polymers can be formed into tubes (page 18, [0145]) and they further teach that the polymer can be formed into a medical implant in the shape of a tube for use in treatment of injury or damage to the peripheral nervous system (page 18, [0146]). Giroux teaches salicylic acid as one of the biologically active agents to be released (page 18, [0144]) and teach as salicylic acid as the biological agent in one preferred embodiment (page 20, [0171]). Thus Giroux teaches a polymer in the form of a tube that degrades to release salicylic acid and anticipates claims 1-7 and 9.

In claims 12-14, applicant claims that the polymer has one or more units of formula I and II. Giroux teaches the same formulas I and II (page 5, [0066-0068]) and thus anticipates claims 12-14.

The above claims are anticipated by Giroux or alternatively are obvious over Giroux. As discussed above, Giroux et al. teaches a polymer that biodegrades and releases an active agent. They clearly teach salicylic acid as an active agent and they teach tubes. The invention of claims 1-7, 9, and 12-14 is clearly within the scope of the teachings of Giroux and would be obvious to one of ordinary skill in the art at the time of the invention. It is noted that while Giroux does not teach use for neural tissue regeneration the claims are directed towards a composition and the intended use does not carry patentable weight. Thus claims 1-7, 9 and 12-14 are alternatively unpatentable over Giroux et al.

Conclusion

Rejection of claims 1-7, 9, 12-14, and 67-76 is deemed proper and is **maintained.**

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 9:30am-7pm Mon-Thu, 9:30am-6pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/622,072

Page 8

Art Unit: 1614

Meghan Finn

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614